L Number	Hits	Search Text	DB	Time stamp
-	2	6235321.pn.	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 13:36
-	2	6253321.pn.	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 14:41
-	2	"WO 9963473"	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 14:43
-	0	US-584525A-$.DID.	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 14:43
-	4	(("5845255") or ("20030036683")).PN.	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 15:06
-	24325	clinical near6 trial	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 15:06
-	6763	(clinical near6 trial) and database	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 15:07
-	5966	((clinical near6 trial) and database) and (rule specification regulation)	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 15:07
-	100	((clinical near6 trial) and database) and (rule specification regulation) with trial	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 15:35
-	100	(((clinical near6 trial) and database) and (rule specification regulation) with trial) and form	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 15:08
-	56	((((clinical near6 trial) and database) and (rule specification regulation) with trial) and form) and (survey question)	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 15:08
-	0	6108635.pn. and (rule specification regulation) near6 trial	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 15:36
-	11	9.	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 15:36
-	41	(((((clinical near6 trial) and database) and (rule specification regulation) with trial) and form) and (survey question)) and (rule specification regulation) near6 trial	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 15:36

-	1	6108635.pn. and (rule specification regulation) with trial	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2004/09/09 15:36

File 348:EUROPEAN PATENTS 1978-2004/Aug W05
(c) 2004 European Patent Office
File 349:PCT FULLTEXT 1979-2002/UB=20040902,UT=20040826
(c) 2004 WIPO/Univentio

Set	Items	Description
S1	22465	(CLINICAL OR CLINICIAN OR MEDICAL OR MEDICINAL OR HOSPITAL OR PHARMACEUTICAL OR DRUG)(1W)(TRIAL? ? OR TEST? ?)
S2	151	S1(7N)(DATABASE? ? OR DATA()BASE? ? OR (INFORMATION OR DATA)(1W)(MANAGEMENT OR MANAGER) OR REPOSITOR??? OR DBMS OR RDBMS OR (MANAGEMENT OR INFORMATION OR DATA)()(SYSTEM OR SOFTWARE))
S3	44	S2(5N)(ESTABLISH? OR GENERAT? OR CREAT???? OR FASHION? OR CONSTRUCT? OR FORM?? OR FORMING OR FORMATION? ? OR PRODUC????? OR DEVELOP? OR BUILT OR BUILD? OR DEFIN??? OR SET????()UP OR DESIGN???)
S4	36	S3 AND IC=G06F
S5	31	S4 AND AC=US/PR
S6	22	S5 AND AY=(1970:2000)/PR
S7	8	S4 AND PY=1970:2000
S8	23	S6:S7
S9	16	S3(100N)(RULE? ? OR REGULATION? ? OR REGULATORY OR POLICY OR POLICIES OR COMPLIANT OR COMPLIANCE OR GUIDELINE? ? OR CONDITION? ?)
S10	6	S8 AND S9
S11	2	PA='PHASE FORWARD INC'
S12	2	S11 AND (RULE? ? OR QUESTION? ?)

10/3,K/1 **(Item 1 from file: 348)**
DIALOG(R)File 348:EUROPEAN PATENTS

01444830
Methods for obtaining and using Haplotype data
Verfahren zur herstellung und verwendung von Haplotype Daten
Procede d'obtention et d'utilisation de donnees sur les haplotypes
PATENT ASSIGNEE:
Genaissance Pharmaceuticals, Inc., (3108670), Five Science Park, New Haven, CT 06511, (US), (Applicant designated States: all)
INVENTOR:
Judson, Richard S., 42 Barker Hill Drive, Guilford, CT 06437, (US)
Windemuth, Andreas K., 91 Center Road, Woodbridge, CT, (US)
Xu, Chuanbo, 524 Opening Hill Road, Madison, CT, (US)
LEGAL REPRESENTATIVE:
Molnia, David (90493), Dorries, Frank-Molnia, Pohlman, Postfach 221661, 80506 Munchen, (DE)
PATENT (CC, No, Kind, Date): EP 1233366 A2 020821 (Basic)
APPLICATION (CC, No, Date): EP 2002007045 000626;
PRIORITY (CC, No, Date): US 141521 990625
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE
EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI
RELATED PARENT NUMBER(S) - PN (AN):
EP 1208421 (EP 2000941722)
INTERNATIONAL PATENT CLASS: **G06F-019/00**
ABSTRACT WORD COUNT: 87
NOTE:
Figure number on first page: NONE

LANGUAGE (Publication,Procedural,Application): English; English; English
FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS A	(English)	200234	722
SPEC A	(English)	200234	33384
Total word count - document A			34106
Total word count - document B			0
Total word count - documents A + B			34106

INTERNATIONAL PATENT CLASS: **G06F-019/00**

...SPECIFICATION by eliminating trial and error administrations of other drugs which would not be expected to work for the disease or **condition** manifested by the patient.
If clinical trials are unsuccessfully completed, a Partner may desire haplotype information for isogenes, and/or...
...isogene clones containing isogenes of the gene, to correlate drug response with haplotype and to use as an aid in **designing** an additional **clinical trial** (or trials), as discussed elsewhere herein.
The **database** and analytical tools of the invention are envisioned to be useful in a variety of settings, including various research settings
...

10/3,K/2 **(Item 2 from file: 348)**
DIALOG(R)File 348:EUROPEAN PATENTS

01444829
Methods for obtaining and using haplotype data
Verfahren zur herstellung und verwendung von Haplotype Daten
Procede d'obtention et d'utilisation de donnees sur les haplotypes
PATENT ASSIGNEE:
Genaissance Pharmaceuticals, Inc., (3108670), Five Science Park, New Haven, CT 06511, (US), (Applicant designated States: all)
INVENTOR:
Judson, Richard S., 42 Barker Hill Drive, Guilford, CT 06437, (US)

Windemuth, Andreas K., 91 Center Road, Woodbridge, CT 06525, (US)
LEGAL REPRESENTATIVE:
Molnia, David (90493), Dorries, Frank-Molnia, Pohlman, Postfach 221661, 80506 Munchen, (DE)
PATENT (CC, No, Kind, Date): EP 1233365 A2 020821 (Basic)
APPLICATION (CC, No, Date): EP 2002007044 000626;
PRIORITY (CC, No, Date): US 141521 990625
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE
EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI
RELATED PARENT NUMBER(S) - PN (AN):
EP 1208421 (EP 2000941722)
INTERNATIONAL PATENT CLASS: **G06F-019/00**
ABSTRACT WORD COUNT: 87
NOTE:
Figure number on first page: 45

LANGUAGE (Publication,Procedural,Application): English; English; English
FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS A	(English)	200234	3955
SPEC A	(English)	200234	33305
Total word count - document A			37260
Total word count - document B			0
Total word count - documents A + B			37260

INTERNATIONAL PATENT CLASS: **G06F-019/00**

...SPECIFICATION by eliminating trial and error administrations of other drugs which would not be expected to work for the disease or **condition** manifested by the patient.
If clinical trials are unsuccessfully completed, a Partner may desire haplotype information for isogenes, and/or...
...isogene clones containing isogenes of the gene, to correlate drug response with haplotype and to use as an aid in **designing** an additional **clinical trial** (or trials), as discussed elsewhere herein.
The **database** and analytical tools of the invention are envisioned to be useful in a variety of settings, including various research settings ...

10/3,K/3 (Item 3 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

01444828
Methods for obtaining and using haplotype data
Verfahren zur herstellung und verwendung von Haplotype Daten
Procede d'obtention et d'utilisation de donnees sur les haplotypes
PATENT ASSIGNEE:
Genaissance Pharmaceuticals, Inc., (3108670), Five Science Park, New Haven, CT 06511, (US), (Applicant designated States: all)
INVENTOR:
Denton, Richard Rex, 129 Hunters Trail, Madison, CT 06443, (US)
Stephens, Joel Claiborne, 46 Crabapple Lane, Guilford, CT 06437, (US)
Judson, Richard S., 42 Barker Hill Drive, Guilford, CT 06437, (US)
Windemuth, Andreas K., 91 Center Road, Woodbridge, CT 06525, (US)
Ruano, Gualberto, 88 Hillside Avenue, Milford, CT 06460, (US)
Xu, Chuanbo, 524 Opening Hill Road, Madison, CT 06443, (US)
LEGAL REPRESENTATIVE:
Molnia, David (90493), Dorries, Frank-Molnia, Pohlman, Postfach 221661, 80506 Munchen, (DE)
PATENT (CC, No, Kind, Date): EP 1233364 A2 020821 (Basic)
APPLICATION (CC, No, Date): EP 2002007038 000626;
PRIORITY (CC, No, Date): US 141521 990625
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE
EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI

RELATED PARENT NUMBER(S) - PN (AN):
EP 1208421 (EP 2000941722)
INTERNATIONAL PATENT CLASS: **G06F-019/00**
ABSTRACT WORD COUNT: 87
NOTE:
Figure number on first page: 45

LANGUAGE (Publication,Procedural,Application): English; English; English
FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS A	(English)	200234	954
SPEC A	(English)	200234	33317
Total word count - document A			34271
Total word count - document B			0
Total word count - documents A + B			34271

INTERNATIONAL PATENT CLASS: **G06F-019/00**

...SPECIFICATION by eliminating trial and error administrations of other drugs which would not be expected to work for the disease or **condition** manifested by the patient.
If clinical trials are unsuccessfully completed, a Partner may desire haplotype information for isogenes, and/or...

...isogene clones containing isogenes of the gene, to correlate drug response with haplotype and to use as an aid in **designing** an additional **clinical trial** (or trials), as discussed elsewhere herein.
The **database** and analytical tools of the invention are envisioned to be useful in a variety of settings, including various research settings ...

10/3,K/4 (Item 1 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
(c) 2004 WIPO/Univentio. All rts. reserv.

00885090 **Image available**
SYSTEM, METHOD, AND USER INTERFACE FOR MANAGING INTERMEDIATE HEALTHCARE FACILITIES OVER COMPUTER NETWORKS
SYSTEME, METHODE ET INTERFACE UTILISATEUR PERMETTANT DE GERER DES UNITES DE SOINS COURANTS SUR DES RESEAUX INFORMATIQUES
Patent Applicant/Assignee:
CENTRALINK LLC, Suite A, 611 North Canon Drive, Beverly Hills, CA 90210, US, US (Residence), US (Nationality)
Inventor(s):
KASIRER Robert, Beverly Hills, CA,
WIELAND Florian, Laguna Hills, CA,
KOONTZ James, Diamond Bar, CA,
MAYNER Steve, Marina Del Rey, CA,
STRUNK Carl, Rancho Palos Verdes, CA,
Legal Representative:
STEWART David L (et al) (agent), McDermott, Will & Emery, 600 13th Street, NW, Washington, DC 20005-3096, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200219221 A1 20020307 (WO 0219221)
Application: WO 2001US27092 20010831 (PCT/WO US0127092)
Priority Application: US 2000230218 20000901; US 2001265186 20010130; US 2001282876 20010411
Designated States:
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)
AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PH PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG UZ VN YU ZA ZW
(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR
(OA) BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG
(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZW

(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 7837

Main International Patent Class: **G06F-017/60**
Fulltext Availability:
Detailed Description

Detailed Description
... services.
Figure 12 is a high level flow chart of an exemplary process for converting @MS data into a searchable **database** for identifying potential **clinical** **trial** candidates and for determining **product** utilization.

Figure 13 is an illustration of a **rules** hierarchy for illustrating **rules** inheritance in accordance with one aspect of the invention.

8
Figures 14A and 14B illustrate high level information flow before...130).

Figure 12 is a high level flow chart of an exemplary process for converting MDS data into a searchable **database** for identifying potential **clinical** **trial** candidates and for determining **product** utilization. At the ICF, a copy of the NMS data from the facility is made (1200) and cleansed or sanitized to remove data from the MDS records or hit the **guidelines** (IM). The cleansed MDS file and transfer-red from the facility to the Central Server over a network (t220) and...

...which is utilized as the object for information retrieval queries by users (1240). A user can then query the query **database** table for potential **clinical** **trial** candidates and/or for **product** utilization (1250).

Figure 13 is an illustration of a **rules** hierarchy for illustrating **rules** inheritance in accordance with one aspect of the invention. The **rules** utilized to implement the invention eacg have a scope of application. **Rules** at a lower level in the hierarchy may inherit characteristics of **rules** higher in the hierarchical level. For example, as shown in Figure 13, a plurality of **rules** may have system-wide application. These **rules** may be inherited by a variety of enterprises and sub-enterprises. For example, North America may constitute an enterprise having...

10/3,K/5 (Item 2 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00831853 **Image available**
USE OF INTERNET SITE AS A REGISTRY FOR RESULTS OF MEDICAL TESTS
UTILISATION DE SITE INTERNET COMME SITE D'ENREGISTREMENT DE RESULTATS DE TESTS MEDICAUX
Patent Applicant/Inventor:
DEMOPULOS Gregory, 6530 83rd Place S.E., Mercer Island, WA 98040, US, US (Residence), US (Nationality)
Legal Representative:
ANDERSON Ronald (agent), Law Offices of Ronald M. Anderson, 600 108th Avenue NE, Suite 507, Bellevue, WA 98004, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200165443 A1 20010907 (WO 0165443)
Application: WO 2001US5662 20010223 (PCT/WO US0105662)
Priority Application: US 2000185562 20000228; US 2000566530 20000508
Designated States:
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)
AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CR CU CZ DE DK DM DZ EE

ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT
LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM
TR TT TZ UA UG UZ VN YU ZA ZW
(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR
(OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 12730

Main International Patent Class: **G06F-017/60**
Fulltext Availability:
Claims

Claim
... verification of the subscriber's identity. In this case, the registry site will simply provide a repository for such data, **creating** a historical **database** of **medical test** results that may be of benefit to the subscriber, and will indicate, in connection with such data, that the identity...

...primary purpose of the service provided to the subscriber by the registry site is to enable proof of a medical **condition** to be presented to a prospective sexual partner of the subscriber based upon the results of one or more medical...

10/3,K/6 (Item 3 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00768562
METHODS FOR OBTAINING AND USING HAPLOTYPE DATA
OBTENTION ET UTILISATION DE DONNEES SUR LES HAPLOTYPES
Patent Applicant/Assignee:
GENAISSANCE PHARMACEUTICALS INC, Five Science Park, New Haven, CT 06511, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
DENTON Richard Rex, 129 Hunters Trail, Madison, CT 06443, US, US (Residence), US (Nationality), (Designated only for: US)
JUDSON Richard S, 42 Baker Hill Drive, Guilford, CT 06437, US, US (Residence), US (Nationality), (Designated only for: US)
RUANO Gualberto, 88 Lawrence Street, New Haven, CT 06511, US, US (Residence), US (Nationality), (Designated only for: US)
STEPHENS Joel Claiborne, 46 Crabapple Lane, Guilford, CT 06437, US, US (Residence), US (Nationality), (Designated only for: US)
WINDEMUTH Andreas K, 91 Center Road, Woodbridge, CT 06524, US, US (Residence), DE (Nationality), (Designated only for: US)
XU Chuanbo, 524 Openint Hill Road, Madison, CT 06443, US, US (Residence), CN (Nationality), (Designated only for: US)
Legal Representative:
MOROZ Eugene (et al) (agent), Morgan & Finnegan, L.L.P., 345 Park Avenue, New York, NY 10154, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200101218 A2-A3 20010104 (WO 0101218)
Application: WO 2000US17540 20000626 (PCT/WO US0017540)
Priority Application: US 99141521 19990625
Parent Application/Grant:
Related by Continuation to: US 99141521 19990625 (CIP)
Designated States:
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)
AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CR CU CZ DE DK DM DZ EE
ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT
LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM
TR TT TZ UA UG US UZ VN YU ZA ZW

(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE
(OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Publication Language: English
Filing Language: English
Fulltext Word Count: 64346
Main International Patent Class: **G06F-007/00**
International Patent Class: **G06F-017/00** ...
Fulltext Availability:
Detailed Description

Detailed Description
... by eliminating trial and error administrations of other drugs which would not be expected to work for the disease or **condition** manifested by the patient.

If clinical trials are unsuccessfully completed, a Partner may desire haplotype inforination for isogenes, and/or...

...isogene clones containing isogenes of the gene, to correlate drug response with haplotype and to use as an aid in **designing** an additional **clinical trial** (or trials), as discussed elsewhere herein.

The **database** and analytical tools of the invention are envisioned to be useful in a variety of settings, including various research settings...

12/5,K/2 (Item 1 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00532121 **Image available**

CLINICAL TRIAL DATA MANAGEMENT SYSTEM AND METHOD
SYSTEME ET PROCEDE DE GESTION DE DONNEES D'ESSAIS CLINIQUES

Patent Applicant/Assignee:
PHASE FORWARD INC
Inventor(s):
BLEICHER Paul A,
STAMOS Nicholas,
KLOFFT Jeffrey P,
DALE Richard M,

Patent and Priority Information (Country, Number, Date):
Patent: WO 9963473 A2 19991209
Application: WO 99US12406 19990603 (PCT/WO US9912406)
Priority Application: US 9892441 19980605
Designated States:
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)
DE GB JP AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE
Main International Patent Class: G06F-019/00
Publication Language: English
Fulltext Availability:
Detailed Description
Claims
Fulltext Word Count: 14603

English Abstract
A system and method for managing clinical trial data includes dynamically generating, at a server, a data entry form to be displayed at a client. The data entry form is generated dynamically in a SGML-derived language. Control elements within the form comprise images which are used to construct the control elements and larger controls. The form is generated from a protocol database and a context received from the client, is populated from the data database, and is published to the client. Templates based on the protocol database comprise several frames including intermediate frames for displaying frame borders which are non-horizontal and non-vertical. If the trial protocol changes during a trial, the generated form is based on the protocol version active at the time data was entered into the form. Inadvertent use of the application is discouraged requiring an authentication procedure and displaying a picture of the authenticated user. Furthermore, help is provided by creating a link between the text of each **question** and information about the **question** . The source of help may be any or all of a protocol document, an investigative brochure, and a study guide. In addition, a user, upon logging in, is presented with a dashboard screen which provides information or links to information such as trial-related news, alerts, statistical information, progress reports and a list of work to be completed.

French Abstract
L'invention concerne un systeme et un procede de gestion de donnees d'essais cliniques. Ce systeme et ce procede consistent a generer de maniere dynamique, sur un serveur, une grille de saisie destinee a etre affichee chez un client. Cette grille de saisie generee de maniere dynamique en un langage derive du SGML. Les elements de commande se trouvant dans la grille comprennent des images qui servent a construire ces elements de commande et des commandes plus importantes. Cette grille est generee a partir d'une base de donnees de protocole tandis qu'un contexte recu du client est equipe a partir de la base de donnees et publie pour le client. Des modeles bases sur la base de donnees de protocole comprennent plusieurs trames composees de trames intermediaires de facon a afficher des limites de trames qui sont non horizontales et non verticales. Si le protocole d'essai est modifie pendant un essai, la grille generee se base sur la version du protocole en activite au moment de l'introduction des donnees dans la grille. Une utilisation de

l'application par inadvertance est evitee grace a une procedure d'identification et a l'affichage d'une photo de l'utilisateur identifie. En outre, une aide est apportee grace a la creation d'un lien entre le texte de chaque **question** et des informations concernant la **question** . La source d'aide peut se presenter sous la forme d'un document de protocole et/ou d'une brochure de recherche et/ou d'un guide d'etudes. En outre, lorsqu'un utilisateur ouvre une session, une unite d'affichage de tableau de bord apparait, laquelle fournit des informations ou des liens avec des informations telles que des nouvelles concernant les essais, des alarmes, des informations statistiques, des rapports provisoires et une liste de travail destinee a etre completee.

Patent Applicant/Assignee:
PHASE FORWARD INC ...
Fulltext Availability:
Detailed Description
Claims

English Abstract
...displaying a picture of the authenticated user. Furthermore, help is provided by creating a link between the text of each **question** and information about the **question** . The source of help may be any or all of a protocol document, an investigative brochure, and a study guide...

French Abstract
...utilisateur identifie. En outre, une aide est apportee grace a la creation d'un lien entre le texte de chaque **question** et des informations concernant la **question** . La source d'aide peut se presenter sous la forme d'un document de protocole et/ou d'une brochure...

Detailed Description
... is itself
based on the protocol version which was active at time data was entered.

Furthermore, in a preferred embodiment, **rules** are associated with the displayed form, and are based on the protocol version which was active at the time of...

...embodiment of
the present invention is the provision of context sensitive help. Preferably, a displayed form has at least one **question** to which a user must respond to provide clinical data. Links are created between the text of each **question** and detailed information related to the **question** . If the user clicks on text of the **question** , detailed information corresponding to the **question** is retrieved from the server is displayed.

Preferably, the detailed information is derived from any or all of three source...markup language (HTML) document. The document
can also include small scripts in a language such as Javascript for implementing certain **rules** at the user's site. Investigative sites 112 include, but are not
5 limited to, hospitals, clinics and independent doctors...

...lab results to name a
few.

As clinical reviewers at the CRO or sponsor examine the answers to the CRF **questions** , they may have
10 **questions** or comments which require responses from the investigation site. These **questions** and comments are referred to as queries. The CI or CRC must be able to respond to a query, usually by attaching a comment to a **question** or CRF, by adding new or additional information
15 to a CRF, or by changing information previously entered

on the protocol, the study
reference manual, a study newsletter, and a list of
frequently asked **questions** . In addition, they must
review information about individual **questions** on the CRF
5 such as getting a list of all previous responses to a
question and viewing the discrepancy criteria for a
question .

During a trial, a CI or CRC may need to communicate
with a representative of the sponsor. For example,
10...

...to the sponsor (Form 1571, lab normals, CVs of
the investigator). As the study progresses, the CRC may
have a **question** or may notice something that would
interest the sponsor. Much of this communication is
15 included in the study files...

...site may want to communicate with another
site. Perhaps an investigation site wants to ask
someone at another site a **question** . These
20 communications are not part of the study data.

In addition to written communication with the
sponsor, frequently the...value is questionable, or
there is some other cause for concern, the data reviewer
issues a query by attaching a **question** or comment to a
question on the CRF.

Before a clinical database can be locked, members
of the review team may he required to sign...

...personnel must see these
messages before continuing.

Data reviewers need to communicate with each other.

A CRA may have a **question** for the medical monitor, or
the medical monitor may notice something that they would
like the CRA to investigate. Unlike...with the information in the
CRFs. This is known as source document verification.

The CPA monitors a CRF at the **question** level, meaning
that part of a CRF could be considered reviewed, but the
rest will still need monitoring at a...the study such as the study
protocol,
the study reference manual, a study newsletter, and a
list of frequently asked **questions** . During the study,
the pharmacist may need to communicate with the sponsor
personnel. As the study progresses, the pharmacist may
have a **question** or may notice something that would be of
interest to the sponsor. Some of these communications
must be included in...has been generated, the form
creation process 207 uses the user request 213 and
descriptor database 219 to determine what **questions** ,
controls and other information should go into the form
in the HTML document 221 previously laid out by the
application...can also contain small
scripted statements written in a language such as
Javascript, which might be used to implement certain
rules . For example, a **rule** might allow patient
temperatures only within a certain range, to protect
against the entering of Celsius temperatures instead of
Fahrenheit. Checking with **rules** at the browser using a
language such as Javascript obviates the extra
transmissions back and forth that would be required if
all checks were to be done at the server. Such **rules**
5 may be based on the protocol which was active at the

time certain data was entered.

In Fig. 4D, an inconsistency in the data has been found. The user has indicated in **Question** 7 that the patient has never smoked, yet in **Question** 9 has indicated that the patient smokes cigarettes. Thus a query 271 has been entered by a CRA asking for further verification and appears on the form for the user to respond to.

Finally, note that the text of each **question** is a link to additional information. For example, the text 271 of **Question** 5, "Weight" is a link to one of several documents explaining weight in the context of the protocol. This is...30 the use of context sensitive help in a Web document. As seen in Fig. 13A, the text of each **question** comprises a link to one of several trial-related documents. For instance, the text 801 "Height" for item 4 is...

Claim
... forms.

9 The method of Claim 7 wherein the form is dynamically generated.

10 The method of Claim 7 wherein **rules** associated with the displayed form are based on the protocol version which was active at the time of entering data...

...A clinical trial data entry method, comprising:
displaying a form on a computer screen, the form having at least one **question** to which a user must respond to provide clinical data;
creating links between text of each **question** and detailed information related to the **question** ;
and
if the user clicks on text of the **question** , displaying detailed information corresponding to the **question** .
12 The method of Claim 11 wherein the detailed information displayed is a help document defining the clinical trial.

13...

...A clinical trial data entry method, comprising:
displaying a form on a computer screen, the form having at least one **question** to which a user must respond to provide clinical data;
upon a user request, displaying detailed information from any or...

...displayed is from a section of the protocol document, investigative brochure, or study guide, which section pertains immediately to the **question** to which the user must respond.

18 A method of constructing a graphical user interface (GUI) clinical trial application, comprising...system for entering clinical trial data,
comprising:
a form displayed on a computer screen, the form having at least one **question** to which a user must respond to provide clinical data; and
links between text of each **question** and detailed information related to the **question** , the

detailed information existing in at least one on line document, such that if the user clicks on text of the **question** , displaying detailed information corresponding to the **question** is displayed.

File 347:JAPIO Nov 1976-2004/May(Updated 040903)
(c) 2004 JPO & JAPIO
File 350:Derwent WPIX 1963-2004/UD,UM &UP=200457
(c) 2004 Thomson Derwent

Set	Items	Description
S1	3145	(CLINICAL OR CLINICIAN OR MEDICAL OR MEDICINAL OR HOSPITAL OR PHARMACEUTICAL OR DRUG)(1W)(TRIAL? ? OR TEST? ?)
S2	57	S1(7N)(DATABASE? ? OR DATA()BASE? ? OR (INFORMATION OR DATA)(1W)(MANAGEMENT OR MANAGER) OR REPOSITOR??? OR DBMS OR RDBMS OR (MANAGEMENT OR INFORMATION OR DATA)()(SYSTEM OR SOFTWARE))
S3	16	S2(5N)(ESTABLISH? OR GENERAT? OR CREAT???? OR FASHION? OR CONSTRUCT? OR FORM?? OR FORMING OR FORMATION? ? OR PRODUC????? OR DEVELOP? OR BUILT OR BUILD? OR DEFIN??? OR SET????()UP OR DESIGN???)
S4	2	S3 AND (RULE? ? OR REGULATION? ? OR REGULATORY OR POLICY OR POLICIES OR COMPLIANT OR COMPLIANCE OR GUIDELINE? ? OR CONDITION? ?)
S5	1295	CLINICAL(1W)TRIAL? ?
S6	8	S5 AND RULE? ?
S7	9	S4 OR S6
S8	1	PA='PHASE FORWARD INC (PHAS-N)'

7/5/1 (Item 1 from file: 350)

DIALOG(R)File 350:Derwent WPIX

015902781 **Image available**
WPI Acc No: 2004-060621/200406
XRPX Acc No: N04-049064

Medical information providing system, has expert system comprising predetermined rules and functioning to analyze portions of record system data stored in database

Patent Assignee: LEVINE J H (LEVI-I)
Inventor: LEVINE J H
Number of Countries: 001 Number of Patents: 001
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
US 20030225597	A1	20031204	US 2002157476	A	20020529	200406	B

Priority Applications (No Type Date): US 2002157476 A 20020529
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 20030225597	A1		14	G06F-017/60	

Abstract (Basic): US 20030225597 A1

NOVELTY - The system has a record system with a database and an expert system. The database is provided for collection, storage, manipulation and output of record system data. An expert system has a set of predetermined **rules** and functioning to analyze portions of the record system data. A professional network comprises medical professionals who supply data to the record system.

USE - Used for creating and using medical information.

ADVANTAGE - The comprehensive database of the record system expedites the research and **clinical trial** process, thereby reducing cost and improving speed to market for new products.

DESCRIPTION OF DRAWING(S) - The drawing shows a flowchart of steps to enroll patients in the medical data providing system.

pp; 14 DwgNo 4/7

Title Terms: MEDICAL; INFORMATION; SYSTEM; EXPERT; SYSTEM; COMPRISE; PREDETERMINED; **RULE** ; FUNCTION; ANALYSE; PORTION; RECORD; SYSTEM; DATA; STORAGE; DATABASE
Derwent Class: S05; T01
International Patent Class (Main): G06F-017/60
File Segment: EPI

7/5/3 (Item 3 from file: 350)

DIALOG(R)File 350:Derwent WPIX

015716866 **Image available**
WPI Acc No: 2003-779066/200373
XRAM Acc No: C03-214507
XRPX Acc No: N03-624339

Deriving an outcome predictor for a data set comprises applying recursive partitioning methodology to the data set using basis functions that are generated for interactions among variables for data set

Patent Assignee: KITCHEN C M (KITC-I); KITCHEN S G (KITC-I)
Inventor: KITCHEN C M; KITCHEN S G
Number of Countries: 103 Number of Patents: 003
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 200376895	A2	20030918	WO 2003US6629	A	20030306	200373	B
US 20030220777	A1	20031127	US 2002361703	P	20020306	200378	
			US 2003378866	A	20030305		
AU 2003223223	A1	20030922	AU 2003223223	A	20030306	200431	

Priority Applications (No Type Date): US 2003378866 A 20030305; US 2002361703 P 20020306
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200376895	A2	E	33	G01N-000/00	

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NI NO NZ OM PH PL PT RO RU SC SD SE SG SK SL TJ TM TN TR TT TZ UA UG UZ VC VN YU ZA ZM ZW

Designated States (Regional): AT BE BG CH CY CZ DE DK EA EE ES FI FR GB GH GM GR HU IE IT KE LS LU MC MW MZ NL OA PT RO SD SE SI SK SL SZ TR TZ UG ZM ZW

US 20030220777 A1	G06G-007/48	Provisional application US 2002361703	
AU 2003223223 A1	G01N-000/00	Based on patent WO 200376895	

Abstract (Basic): WO 200376895 A2

NOVELTY - Deriving an outcome predictor for a data set, where variables affect outcome for the data set, comprising generating basis functions for interactions among the variables for the data set using a flexible nonparametric tool; and applying a recursive partitioning methodology to the data set, using the generated basis functions, to produce the outcome predictor, is new.

DETAILED DESCRIPTION - INDEPENDENT CLAIMS are also included for:

(a) a system for deriving an outcome predictor for a data set, comprising a generating mechanism for generating the basis functions for interactions among the variables for the data set using the flexible nonparametric tool; and an application mechanism for applying a recursive partitioning methodology to the data set, using the generated functions, to produce the outcome predictor; and

(b) a computer program product, comprising a computer usable medium having a control logic stored for causing a computer to derive the outcome predictor for a data set, where the control logic comprises a first computer readable program code for causing the computer to generate the basis functions; and a second computer readable program code for causing the computer to apply the recursive partitioning methodology to the data set.

USE - The method is used for deriving an outcome predictor for a data set. The outcome predictor comprises a decision tree for a genetic mapping study used to determine gene and environment interactions. The outcome predictor comprises a decision tree for use as a mass marketing study for a product. It relates the genotypic information to treatment type(s) including an administered drug. The outcome predictor is used to determine a personalized treatment regime for an individual, where the individual has a disease and a genotype, where the outcome predictor comprises a decision tree containing a result for the genotype of the individual, having a disease, e.g. human immunodeficiency virus (HIV), autism, AIDS, a blood disease, hepatitis, heart disease, diabetes, epilepsy, cancer, a mental disorder, a neurological disorder, liver disease, a urological disorder, a kidney disorder, or a congenital defect (all claimed). It could be used to identify genetic factors that render individuals susceptible to a variety of inherited and acquired diseases, as well as to develop drug resistance profiles that result from treating these ailments. It can be used to sort out variables that lead to the development of autism. It can be employed to predict a single variable from variables in many different areas, including but not limited to the medical, behavioral, biologic, physical, engineering, and economic sciences, as well as in marketing and business. It is generally beneficial in deriving the relationship between one continuous outcome variable with many predictors.

ADVANTAGE - The inventive method accurately predicts outcomes to problems having complex variables. It predicts treatment outcomes, e.g. drug response, for diseases involving numerous complex variables. It determines effectiveness of medical treatment (e.g., drug effectiveness) for particular conditions, e.g. diseases. It is usable to predict in **clinical trials** whether a subject is likely to be a placebo responder. It can overcome the identification problem by reducing the dimension of the parameter space and identifying important interactions.

DESCRIPTION OF DRAWING(S) - The figure presents various components of a standalone system for deriving an outcome predictor for a data set having variables affecting outcome.

pp; 33 DwgNo 1/6

Title Terms: DERIVATIVE; PREDICT; DATA; SET; COMPRISE; APPLY; RECURSIVE; PARTITION; DATA; SET; BASIS; FUNCTION; GENERATE; INTERACT; VARIABLE; DATA ; SET

Derwent Class: B04; D16; S05; T01

International Patent Class (Main): G01N-000/00; G06G-007/48

International Patent Class (Additional): G06G-007/58

File Segment: CPI; EPI

7/5/5 (Item 5 from file: 350)

DIALOG(R)File 350:Derwent WPIX

015030844 **Image available**

WPI Acc No: 2003-091361/200308

XRPX Acc No: N03-072296

Human behavior prediction method in clinical trials **, involves generating predictive algorithm for predicting human behavior, which is translated into prediction** rule **for use with** clinical trial

Patent Assignee: HUFFORD M R (HUFF-I); PATY J A (PATY-I); SHIFFMAN S (SHIF-I)

Inventor: HUFFORD M R; PATY J A; SHIFFMAN S

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
US 20020143577	A1	20021003	US 2001825534	A	20010402	200308	B

Priority Applications (No Type Date): US 2001825534 A 20010402

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 20020143577	A1		11	G06F-017/60	

Abstract (Basic): US 20020143577 A1

NOVELTY - A predictive algorithm for predicting the human behavior with respect to a **clinical trial** is generated. The predictive algorithm is translated into prediction **rule** for use with a **clinical trial** .

DETAILED DESCRIPTION - INDEPENDENT CLAIMS are included for the following:

(1) Human behavior determination method;

(2) Human behavior abnormality detection method;

(3) Recorded medium storing instructions for predicting human behavior.

USE - For predicting human behavior during **clinical trials** .

ADVANTAGE - The human behavior during a **clinical trial** is predicted and tracked reliably with increased statistical power, reduced **clinical trial** costs and reduced **clinical trial** time.

DESCRIPTION OF DRAWING(S) - The figure shows the flowchart of the human behavior prediction method.

pp; 11 DwgNo 2/2

Title Terms: HUMAN; BEHAVE; PREDICT; METHOD; CLINICAL; GENERATE; PREDICT; ALGORITHM; PREDICT; HUMAN; BEHAVE; TRANSLATION; PREDICT; **RULE** ; CLINICAL ; TRIAL

Derwent Class: S05; T01

International Patent Class (Main): G06F-017/60

File Segment: EPI

7/5/7 (Item 7 from file: 350)

DIALOG(R)File 350:Derwent WPIX

014507997 **Image available**

WPI Acc No: 2002-328700/200236

XRAM Acc No: C02-094913
XRPX Acc No: N02-257952

Creation system for generating customized database management system, comprises computer that combines data capacity of database management systems with customization features

Patent Assignee: DURKALSKI W P (DURK-I)
Inventor: DURKALSKI W P
Number of Countries: 001 Number of Patents: 001
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20020023083	A1	20020221	US 2000197648	P	20000417	200236 B
			US 2001836653	A	20010417	

Priority Applications (No Type Date): US 2000197648 P 20000417; US 2001836653 A 20010417
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 20020023083	A1		17	G06F-007/00	Provisional application US 2000197648

Abstract (Basic): US 20020023083 A1

NOVELTY - A creation system comprises a computer that combines the immense data capacity of database management systems with the customization features necessary to accommodate complexities unique to clinical traits specification and related **guidelines** .

DETAILED DESCRIPTION - A creation system comprises a computer configured to execute:

(i) a first routine for asking a user with question(s) related to a desired application for a customized database management system, and for receiving answer(s) from the user;

(ii) a second routine for retrieving a set of **rules** associated with the desired application;

(iii) a third routine for processing an analysis of the answer and set of **rules** ; and

(iv) a fourth routine for generating the customized relational database management system.

An INDEPENDENT CLAIM is also included for a method of creating a customized database management system.

USE - For **generating** a customized database **management system** used in the administration and management of **clinical trials** .

ADVANTAGE - The invention enables a user without training or programming knowledge to rapidly build a CTDBMS. It also allows the user to create one or more CTDBMS software applications. It makes it possible to develop, generate and operate a CTDBMS entirely within a single Web page or at a common Web site, thus eliminating the need for costly, external databases and computers.

DESCRIPTION OF DRAWING(S) - The figure is a diagram showing the administrative portion of a system.

pp; 17 DwgNo 1/10

Title Terms: CREATION; SYSTEM; GENERATE; CUSTOMISATION; DATABASE; MANAGEMENT; SYSTEM; COMPRISE; COMPUTER; COMBINATION; DATA; CAPACITY; DATABASE; MANAGEMENT; SYSTEM; CUSTOMISATION; FEATURE
Derwent Class: B04; S05; T01
International Patent Class (Main): G06F-007/00
File Segment: CPI; EPI

```
File 155:MEDLINE(R) 1951-2004/Sep W1
         (c) format only 2004 The Dialog Corp.
File   5:Biosis Previews(R) 1969-2004/Aug W5
         (c) 2004 BIOSIS
File  73:EMBASE 1974-2004/Aug W5
         (c) 2004 Elsevier Science B.V.
File   2:INSPEC 1969-2004/Aug W5
         (c) 2004 Institution of Electrical Engineers
File 144:Pascal 1973-2004/Aug W5
         (c) 2004 INIST/CNRS
File   6:NTIS 1964-2004/Aug W4
         (c) 2004 NTIS, Intl Cpyrght All Rights Res
File   8:Ei Compendex(R) 1970-2004/Aug W5
         (c) 2004 Elsevier Eng.  Info. Inc.
File  34:SciSearch(R) Cited Ref Sci 1990-2004/Aug W5
         (c) 2004 Inst for Sci Info
File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec
         (c) 1998 Inst for Sci Info
File  94:JICST-EPlus 1985-2004/Aug W2
         (c)2004 Japan Science and Tech Corp(JST)
File  35:Dissertation Abs Online 1861-2004/Aug
         (c) 2004 ProQuest Info&Learning
File  65:Inside Conferences 1993-2004/Sep W1
         (c) 2004 BLDSC all rts. reserv.
File 256:TecInfoSource 82-2004/Jul
         (c)2004 Info.Sources Inc
File 202:Info. Sci. & Tech. Abs. 1966-2004/Jul 12
         (c) 2004 EBSCO Publishing
File 233:Internet & Personal Comp. Abs. 1981-2003/Sep
         (c) 2003 EBSCO Pub.
File 483:Newspaper Abs Daily 1986-2004/Sep 07
         (c) 2004 ProQuest Info&Learning
File  99:Wilson Appl. Sci & Tech Abs 1983-2004/Jul
         (c) 2004 The HW Wilson Co.
File 583:Gale Group Globalbase(TM) 1986-2002/Dec 13
         (c) 2002 The Gale Group
File 266:FEDRIP 2004/Jun
         Comp & dist by NTIS, Intl Copyright All Rights Res
File  95:TEME-Technology & Management 1989-2004/Jun W1
         (c) 2004 FIZ TECHNIK
File 438:Library Lit. & Info. Science 1984-2004/Jul
         (c) 2004 The HW Wilson Co

Set     Items   Description
S1    1059051   (CLINICAL OR CLINICIAN OR MEDICAL OR MEDICINAL OR HOSPITAL
              OR PHARMACEUTICAL OR DRUG)(1W)(TRIAL? ? OR TEST? ?)
S2       2798   S1(7N)(DATABASE? ? OR DATA()BASE? ? OR (INFORMATION OR DAT-
              A)(1W)(MANAGEMENT OR MANAGER) OR REPOSITOR??? OR DBMS OR RDBMS
               OR (MANAGEMENT OR INFORMATION OR DATA)()(SYSTEM OR SOFTWARE))
S3        373   S2(5N)(ESTABLISH? OR GENERAT? OR CREAT???? OR FASHION? OR -
              CONSTRUCT? OR FORM?? OR FORMING OR FORMATION? ? OR PRODUC?????
               OR DEVELOP? OR BUILT OR BUILD? OR DEFIN??? OR SET????()UP OR
              DESIGN???)
S4         92   S3 AND (RULE? ? OR REGULATION? ? OR REGULATORY OR POLICY OR
               POLICIES OR COMPLIANT OR COMPLIANCE OR GUIDELINE? ? OR CONDI-
              TION? ?)
S5         59   RD (unique items)
S6         42   S5 NOT PY=2001:2004
S7         39   S6 AND CLINICAL(1W)TRIAL? ?
S8          2   S6 AND RULE? ?
S9         37   S7 NOT S8
```

8/5/1 (Item 1 from file: 144)
DIALOG(R)File 144:Pascal

13739523 PASCAL No.: 98-0432013

The role of the WHO Programme on International Drug Monitoring in coordinating worldwide Drug safety efforts

OLSSON S
External Affairs, The Uppsala Monitoring Centre, Uppsala, Sweden

Journal: Drug safety, 1998, 19 (1) 1-10
ISSN: 0114-5916 Availability: INIST-21755; 354000072470190010
No. of Refs.: 30 ref.
Document Type: P (Serial) ; A (Analytic)
Country of Publication: New Zealand
Language: English

The rationale for setting up the WHO International Programme for Adverse Reaction Monitoring. 30 years ago was to make it possible to identify rare adverse drug reactions (ADRs) that could not he found through clinical trial programmes. It became evident that maintaining an international database of ADR case reports and a network of institutions and scientists concerned with drug safety issues provides great additional gains when compared with operating in isolation. Thus. the scope of the WHO programme has expanded over time to accommodate the expansion of the field of drug safety monitoring. now often named pharmaco-vigilance. The international centre. the WHO Collaborating Centre for International Drug Monitoring in Uppsala (now known as the Uppsala Monitoring Centre (UMC)), maintains the international database and serves the national centres associated with the WHO programme: however, the role of the centre is expanding allowing it to play a leading role in global drug safety monitoring, The national centres are appointed by the governments of each of the countries participating in the WHO programme. These centres are responsible for collecting spontaneous ADR reports originating from health professionals. 49 countries are currently contributing case information and are full members of the programme; an additional 11 countries have applied for membership but have still not submitted any reports. The annual influx of reports is currently fluctuating at around 150 000 reports. In its development, the data collected by the WHO programme was guarded by strong **rules** SUB o SUB f SUB c SUB o SUB n SUB f SUB i SUB d SUB e SUB n SUB t SUB i SUB a SUB l SUB i SUB t SUB y SUB . In some SUB m SUB e SUB m SUB b SUB e SUB r SUB c SUB o SUB u SUB n SUB t SUB r SUB i SUB e SUB s SUB . SUB SUB h SUB o SUB w SUB e SUB v SUB e SUB r SUB , case data. with the important exception of reporter and patient identities. has always been public information. The UMC has made it a priority to try to create an atmosphere of openness and trust between all parties involved in drug safety assessment, which will eventually enable general sharing of available data and an extended analysis and use of the data collected. The WHO network represents the wealth of competence and experience that is at the disposal of countries wishing to join the international pharmacovigilance community.

English Descriptors: **Database** ; Drug; Toxicity; **Clinical trial** ; Pharmacovigilance; Information; Confidentiality; Research and **development** ; Review

French Descriptors: Base donnee; Medicament; Toxicite; Essai clinique; Pharmacovigilance; Information; Confidentialite; Recherche developpement; Article synthese

Classification Codes: 002B02U10; 002B02A06

8/5/2 (Item 1 from file: 35)
DIALOG(R)File 35:Dissertation Abs Online

01808698 ORDER NO: AADAA-I9938598

A knowledge-based approach to the design and automated generation of clinical trial management systems

Author: Shaban, Sami Fuad
Degree: Ph.D.
Year: 1999
Corporate Source/Institution: Medical University of South Carolina (0122)
Director: Zhen Zhang
Source: VOLUME 60/07-B OF DISSERTATION ABSTRACTS INTERNATIONAL. PAGE 3401. 163 PAGES
Descriptors: ENGINEERING, BIOMEDICAL ; COMPUTER SCIENCE ; HEALTH SCIENCES, HEALTH CARE MANAGEMENT ; ARTIFICIAL INTELLIGENCE
Descriptor Codes: 0541; 0984; 0769; 0800
ISBN: 0-599-39882-5

A novel approach is presented in which a common core set of concepts and knowledge of the classic randomized multicenter clinical trial (randomized clinical trial or RCT), represented as statements of **rules** , is used to construct an abstract model to help the investigator characterize a specific RCT and then deploy a management system for it. This RCT model is developed along several dimensions which are clinical trial theory, clinical trial operations, and clinical trial storage. These dimensions enable the management of the trial and not only the data in the trial. Complete clinical trial management includes the operational flow of the trial, participant randomization, participant eligibility checking, trial event and status sequencing, participant event and status sequencing, schedule **rule** storage and modification, participant calendar generation, as well as participant data entry, storage, and retrieval. In this knowledge-based system, the abstract model representation is implemented using a relational database knowledge representation scheme. During the trial design stage, the representation of the RCT model serves to guide the investigator through the process of defining the necessary parameters of the desired trial. With such user-provided trial specifications, the system will then utilize its knowledge-base to instantiate a complete software system for management of the trial, including collection of participant-specific data. This automatically generated system is web-based and relational database-driven to facilitate platform independence.

The abstract RCT model provides structural control and guidance as to how an instantiated trial is to be conducted and when particular tools are to be used in the trial's operation. A user-friendly environment allows clinical investigators to directly specify their own **clinical trials** and **generate** a software **management system** to support the launching and operation of the clinical trial as well as the distribution and collection of trial information. This **rule** -based approach to the design of clinical trial management systems is of great benefit to clinical trial investigators who now have a way of defining status and scheduling **rules** specifically for their study and have this definition directly reflected in the operation of the clinical trial management system.

9/5/9 (Item 9 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

11117818 PMID: 11079985
Towards a common framework for clinical trials **information systems.**
Salgado N C; Gouveia-Oliveira A
Datamedica Ltd. and Department of Biomathematics, Lisbon Medical School, Lisbon, Portugal.
Proceedings / AMIA ... Annual Symposium. AMIA Symposium (United States) 2000, p754-8, ISSN 1531-605X Journal Code: 100883449
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed
Subfile: INDEX MEDICUS
This work describes the strategies for data modeling and implementation and the general architecture of COATI, a **Clinical Trials information system** that has been in **production** for more than three years. We discuss how the ICH **guidelines** influenced the system design, how we used conventional relational and EAV tables and how we integrated third-party software packages into our system. We describe a new architecture that forms the basis of a common framework for **Clinical Trials** information systems. This structure is based on the concept of a Common Information Framework (CIF). We have defined standard objects and corresponding methods for the CIF as an essential step towards the development of **Clinical Trials** Informatics.
Tags: Human
Descriptors: **Clinical Trials** ; *Information Systems; *Software; Computer Systems; Databases; Systems Integration
Record Date Created: 20010110
Record Date Completed: 20010308

9/5/10 (Item 10 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

10722770 PMID: 10843250
Integration of computer-assembled digital images and text data as evidence for the oncological record.
Liu J M; Wu H W; Chen W S; Lin W C; Chao Y; Lui W Y; Whang-Peng J
Division of Cancer Research, National Health Research Institutes, Veterans General Hospital-Taipei and National Yang Ming University, Taiwan, Republic of China.
Journal of digital imaging - the official journal of the Society for Computer Applications in Radiology (UNITED STATES) May 2000, 13 (2) p55-9, ISSN 0897-1889 Journal Code: 9100529
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed
Subfile: INDEX MEDICUS
Digitally created visual images of pertinent patient data have been integrated with text information to formulate a visual evaluation and summary sheet (VESS) using computer processing. The VESS incorporates images of a patient's physical appearance, radiological images, pharmacokinetic graphs, and text information into a 1-page document of the patient's **condition** . Thus, computer processing of digital images and other information helps to refine patient data presentation, analysis, interpretation, and communication. This **form** of **data management** is especially valuable in oncological research, where **clinical trials** demand rapid, ongoing assessment of results and analysis of large amounts of data. The VESS is an effective mechanism for monitoring both the progress of individual patients and the endpoints of the overall **clinical trial** .
Tags: Comparative Study; Human; Support, Non-U.S. Gov't
Descriptors: *Automatic Data Processing; *Diagnostic Imaging--methods--MT

; *Image Processing, Computer-Assisted; *Medical Audit--methods--MT; *Medical Oncology--methods--MT; *Medical Records Systems, Computerized --organization and administration--OG; Automatic Data Processing--methods --MT; Image Processing, Computer-Assisted--methods--MT; Neoplasms --diagnosis--DI
Record Date Created: 20000918
Record Date Completed: 20000918

9/5/11 (Item 11 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

09261045 PMID: 1807647
Evaluation of benefits derived from a computerized data management system for clinical trials **data.**
Elting L S; Bodey G P
Department of Medical Specialties, University of Texas M. D. Anderson Cancer Center, Houston 77030.
Proceedings / the ... Annual Symposium on Computer Application sic in Medical Care. Symposium on Computer Applications in Medical Care (UNITED STATES) 1991, p48-52, ISSN 0195-4210 Journal Code: 8113685
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed
Subfile: INDEX MEDICUS
Identification and reporting of adverse events is an important responsibility of investigators conducting **clinical trials** of new pharmaceutical compounds. We have **designed** and implemented a computerized **data management system** for **clinical trials** data and have evaluated its performance in managing adverse event information from clinical studies. All cases in which adverse event occurred and a random sample of cases without adverse events were selected from two **clinical trials** managed with the new computerized system and compared with identically selected cases from two **clinical trials** managed with the paper system. Rates of transcription errors, data selection errors and failure to identify adverse events were examined by logistic regression. Analysis of variance of the time required to evaluate clinical information or report adverse events to sponsors was also conducted. Implementation of the computer system resulted in significantly fewer errors in data transcription (17% vs 0%; P less than 0.001) and fewer cases in which adverse events were overlooked (35% vs 3%; P less than 0.001). However, data selection errors were more common using the computer system (2% vs 8%; P = 0.03) because the items evaluated were transferred electronically, rather than selected for appropriateness by a clinician. The average time required to evaluate clinical information and to report adverse event information to sponsoring agencies has been reduced by 2-4 months (P less than 0.001) depending on the severity of the event. This reduction has improved **compliance** with federal **regulations** governing the responsibilities of clinical investigators. It has also permitted early identification of toxicities and appropriate amendment of research protocols, thus reducing risk to patients enrolled in **clinical trials** .
Tags: Human
Descriptors: Adverse Drug Reaction Reporting Systems; * **Clinical Trials** --methods--MT; *Drugs, Investigational--adverse effects--AE; *Information Systems; Adverse Drug Reaction Reporting Systems--standards--ST; Analysis of Variance; Bias (Epidemiology); Data Collection--standards--ST; Evaluation Studies; Information Systems--standards--ST; Logistic Models
CAS Registry No.: 0 (Drugs, Investigational)
Record Date Created: 19920521
Record Date Completed: 19920521

9/5/13 (Item 13 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

08495797 PMID: 2325169
Improving the record of patient assessment in the trauma room.
Walters B C; McNeill I
Regional Trauma Unit, Sunnybrook Medical Centre, Toronto, Ontario, Canada.
Journal of trauma (UNITED STATES) Apr 1990, 30 (4) p398-409, ISSN 0022-5282 Journal Code: 0376373
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed
Subfile: AIM; INDEX MEDICUS
To facilitate clinical research at the Regional Trauma Unit at Sunnybrook Medical Centre in Toronto, it was decided to attempt to improve the quality and quantity of clinical patient information obtained at initial assessment in the Trauma Room. Standardized patient forms were introduced to replace the narrative record, including forms for the Trauma Team Leader, Anesthesia, General Surgery, Neurosurgery, Orthopedic Surgery, and Plastic Surgery. These forms were evaluated in this study which compared 100 charts generated before introduction of the forms to 100 charts generated following the implementation of the forms, with respect to certain items of patient demography and clinical **condition** . There was a statistically significant improvement in amount of information collected and in a format which facilitates data storage and retrieval. This, in turn, **establishes** an excellent standardized **database** for **clinical trials** in trauma care.
Tags: Human
Descriptors: *Medical Records--standards--ST; *Wounds and Injuries --diagnosis--DI; Emergency Medical Service Communication Systems; Medical Audit; Patient Care Team; Physical Examination--standards--ST; Quality Assurance, Health Care
Record Date Created: 19900515
Record Date Completed: 19900515

9/5/18 (Item 3 from file: 73)
DIALOG(R)File 73:EMBASE

07638406 EMBASE No: 1999104924
Validating computer systems for clinical trials **, part 2. The supplier audit**
Benghiat G.; Miller A.; Bleicher P.
G. Benghiat, Phase Forward Incorporated, 610 Lincoln Street, Waltham, MA 02451 United States
AUTHOR EMAIL: paul.bleicher@phaseforward.com
BioPharm (BIOPHARM) (United States) 1999, 12/3 (51-54)
CODEN: BPRME ISSN: 1040-8304
DOCUMENT TYPE: Journal; Review
LANGUAGE: ENGLISH SUMMARY LANGUAGE: ENGLISH
NUMBER OF REFERENCES: 12

A supplier of **clinical trial data management software** should demonstrate control of its **development** process. Look for integrated software verification and validation, good documentation, multitiered testing protocols, and a system for tracking program defects.

MEDICAL DESCRIPTORS:
*computer system
computer program; documentation; validation process; **policy** ; decision making; good clinical practice; review
SECTION HEADINGS:
027 Biophysics, Bioengineering and Medical Instrumentation
039 Pharmacy

9/5/19 (Item 4 from file: 73)
DIALOG(R)File 73:EMBASE

06775962 EMBASE No: 1997057456
Help software for the dispensation and management of drugs in clinical trials : **Conception and evaluation**
AIDE A LA GESTION ET A LA DISPENSATION DES MEDICAMENTS EN ESSAIS CLINIQUES: CONCEPTION ET EVALUATION D'UN LOGICIEL
Portier E.; Le Cosquer A.C.; Bernheim C.
E. Portier, Service Pharmacie, Hopital d'Enfants Armand-Trousseau, 26, Avenue Arnold-Netter, 75012 Paris France
Journal de Pharmacie Clinique (J. PHARM. CLIN.) (France) 1996, 15/SPEC. ISS. (72-73)
CODEN: JPCLD ISSN: 0291-1981
DOCUMENT TYPE: Journal; Conference Paper
LANGUAGE: FRENCH SUMMARY LANGUAGE: FRENCH; ENGLISH
NUMBER OF REFERENCES: 3

Gestec, a help software for the dispensation and management of drugs in **clinical trials** , was **developed** with the **database** Paradox for Windows(TM). Gestec is composed of different modules: Reports, Trials cards, Patients/Dispensations, Stocks management. One of the reports points out each treatment which is out-of-date within three months. Whenever you dispense, Gestec verifies that the trial is really in process, that the precriber is fully authorised and that the lot remains in stock and is not out-of-date; otherwise, the user is warned. Then the dispensation is printed and stocks are updated. A global distribution mode is included but is deactivated by default. Practical modalities of dispensation are accessible at any time. A one-year evaluation at A. Trousseau Hospital, concerned about thirty **clinical trials** . Gestec allowed us to gain time while elaborating closure schedules, allowed earlier supply and an easier management of stocks and validity dates.

MEDICAL DESCRIPTORS:
* **clinical trial** ; *computer program
computer assisted drug therapy; conference paper; monitoring
SECTION HEADINGS:
036 Health **Policy** , Economics and Management
030 Clinical and Experimental Pharmacology

9/5/20 (Item 5 from file: 73)
DIALOG(R)File 73:EMBASE

06408568 EMBASE No: 1996072123
A worldwide strategy for dictionary management
Dutar C.; Otun E.O.
Rhone Poulenc Rorer, Data Management, 20 avenue Raymond Aron,92165 Antony Cedex France
Drug Information Journal (DRUG INF. J.) (United States) 1996, 30/1 (137-142)
CODEN: DGIJB ISSN: 0092-8615
DOCUMENT TYPE: Journal; Review
LANGUAGE: ENGLISH SUMMARY LANGUAGE: ENGLISH

The global integration of data gives rise to special difficulties when there are variations in **database design** , especially if **clinical trials** are conducted across national boundaries without standardization. With more emphasis now being placed on distributed worldwide systems for collection and storage of clinical data, a consistent approach must be maintained in the global management of clinical dictionaries. This paper outlines the Rhone- Poulenc Rorer approach to dictionary management across national boundaries. The paper will also discuss the technical and procedural issues with emphasis on dictionary management systems, and the integration into corporate database strategies.

MEDICAL DESCRIPTORS:
* **clinical trial** ; *information processing

data base; drug industry; food and drug administration; nomenclature; priority journal; review; standardization; world health organization
SECTION HEADINGS:
027 Biophysics, Bioengineering and Medical Instrumentation
036 Health **Policy** , Economics and Management

9/5/21 (Item 6 from file: 73)
DIALOG(R)File 73:EMBASE

06391736 EMBASE No: 1996040253
Follow-up and control of clinical trials . Creation **of a** database
SEGUIMIENTO Y CONTROL DE LOS ENSAYOS CLINICOS. ELABORACION DE UNA BASE DE DATOS
Carmona Ibanez G.; Torregrosa Sanchez R.; Lopez Briz E.
Servicio de Farmacia, Hospital General Universitario, Avda. Tres Cruces, s/n,46014 Valencia Spain
Farmacia Hospitalaria (FARM. HOSP.) (Spain) 1995, 19/5 (295-298)
CODEN: FAHOE ISSN: 1130-6343
DOCUMENT TYPE: Journal; Article
LANGUAGE: SPANISH SUMMARY LANGUAGE: ENGLISH; SPANISH

The aim of this study is to present an application software that easies the follow up of **clinical trials** and clinical studies from their opening demand to the Ethics Committee for Critical Research to their ending. The application software is designed in Dbase-4 for DOS environments and DBFAST for Windows environments. The application consists of four databases: opened **clinical trials** , finished **clinical trials** , rejected **clinical trials** and clinical studies. The opened and finished **clinical trials** databases are interconnected. Databases' fields keep the most important data related to the **clinical trials** and studies. As a result, the application improve the accomplishment of the related laws and good clinical practice procedures. Besides, the application is a helpful instrument for the tasks of the Ethics Committee for Clinical Research.

19/3,K/1 (Item 1 from file: 9)
DIALOG(R)File 9:Business & Industry(R)
(c) 2004 The Gale Group. All rts. reserv.

2954178 Supplier Number: 02954178 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Public CROs: Quintiles Transnational Corp. (Part 2 of 2)
(In 1999, Quintiles Transnational Corp earned net sales totaling $1,607,087,000, with total expenses of $1,470,732,000, ranking second in a list of top public contract research organizations by 1999 revenue)
R&D Directions, v 6, n 8, p 107+
September 2000
DOCUMENT TYPE: Journal; Cover Story ISSN: 1079-9397 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 1837

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...approval of its product, Gingkonin. Those services include preparing the investigational new drug application, protocol **design** , **regulatory** consulting, **clinical trial** management, **data management** , data collection and analysis, report drafting, and submission of a new drug application to the...

19/3,K/2 (Item 2 from file: 9)
DIALOG(R)File 9:Business & Industry(R)
(c) 2004 The Gale Group. All rts. reserv.

2951497 Supplier Number: 02951497 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Public CROs: ICON Plc
(In 1999, ICON Plc earned net sales totaling $80,767,000, with total expenses of $74,236,000, ranking in twelfth place for public contract research organizations by 1999 revenue)
R&D Directions, v 6, n 8, p 82+
September 2000
DOCUMENT TYPE: Journal; Cover Story ISSN: 1079-9397 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 1414

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...worldwide. The company's clinical research services is primarily focused on Phase II to IV **clinical trials** and includes **clinical trials** management, clinical **data management** , study **design** , biostatistical analysis, laboratory services, and **regulatory** affairs consulting. Icon's experience covers all major therapeutic areas, with particular strengths in antiinfectives...

19/3,K/3 (Item 3 from file: 9)
DIALOG(R)File 9:Business & Industry(R)
(c) 2004 The Gale Group. All rts. reserv.

2951493 Supplier Number: 02951493 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Public CROs: Covalent Group Inc.
(In 1999, Covalent Group Inc earned 1999 net sales of $14,747,000, with total expenses of $12,573,000, ranking seventeenth in a list of top public contract research organizations by 1999 revenue)
R&D Directions, v 6, n 8, p 66+
September 2000
DOCUMENT TYPE: Journal; Cover Story ISSN: 1079-9397 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 2556

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...several months.

In addition, the company offers a full array of integrated services including study **design , clinical trial** monitoring and management, **data management ,** biostatistical analysis, and **regulatory** affairs services. Among its most popular and innovative services are TeleTrial and Virtual HouseCall.
TeleTrial...

19/3,K/4 (Item 4 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

2618808 Supplier Number: 02618808 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Public CROs: Kendle International Inc.
(Kendle International ranked 10 out of the 23 publicly-traded contract research organizations by total group revenue with a net revenue in 1998 of $89.5 mil)
R&D Directions, v 5, n 8, p 114+
September 1999
DOCUMENT TYPE: Journal; Company Overview ISSN: 1079-9397 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 1883

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...and Chief Operating Officer Chris Bergen.

Kendle's services include Phase I to Phase IV **clinical - trial design** and management, clinical **data management ,** biostatistical analysis, medical writing, pharmacokinetics, pharmacodynamics, special populations, and **regulatory** consultation. The company specializes in cardiovascular, central nervous system, gastrointestinal, immunological, oncological, respiratory, and skeletal...

19/3,K/5 (Item 5 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

2346740 Supplier Number: 02346740 (USE FORMAT 7 OR 9 FOR FULLTEXT)
All ethical pharmaceuticals-contract research and development
(World: Pharmaceutical industry R&D spending currently totals over $35 bil/yr, of which clinical trial research accounts for about $22bil)
Medical & Healthcare Marketplace Guide, v 1, p I-131+
1998
DOCUMENT TYPE: Journal (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 1600

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...must be able to manage a project from the initial stages of protocol and study **design ,** through **clinical trials** management and **data management ,** to **regulatory** and medical affairs consulting.

- integrated clinical data management -- A key constraint in accelerating the drug...

...collect, edit and analyze the data from up to several thousand patients with various clinical **conditions** from many geographically dispersed sites in an efficient manner. The data must then be standardized...

19/3,K/6 (Item 6 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

2298578 Supplier Number: 02298578 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Kendle International Inc
(Kendle International Inc recently completed a stock offering, with proceeds totaling $51.7 mil)
PharmaBusiness, p 62+
September 1998
DOCUMENT TYPE: Journal ISSN: 1002-1450 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 1475

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...Services include Phase I through IV clinical trial management, clinical data management, statistical analysis, and **regulatory** consultation and representation. During 1997, the company acquired two European-based contract research organizations: U...

...Gene provides a full range of clinical drug development services, including Phase II through IV **clinical - trial design** and management, **data management** , statistical analysis, as well as Phase I and IIa research studies at its 42-bed...

19/3,K/7 (Item 7 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

1995743 Supplier Number: 01995743 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Annual Report: Leading CROs: Pharmaceutical Product Development Inc - Ranked 3
(Pharmaceutical Product Development is the 3rd ranked contract research organization, in 1996 its worldwide net revenue was $197.7 96 mil)
R&D Directions, v 3, n 5, p 53+
September 1997
DOCUMENT TYPE: Journal ISSN: 1051-6778 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 1353

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...expertise

Services offered by Pharmaceutical Product Development

* Bioanalytical laboratory services

* Biostatistical analysis
* Case report form **design**

* Clinical supplies

* **Clinical trials** management

* Computer-assisted new drug application

* **Data management**

* Database **design**

* Health economic studies

* Laboratory services

* Outcomes research

* Patient enrollment

* Pharmacoeconomic studies
* Phase I testing

* Phase...

...Postmarketing studies

* Product registration

* Protocol design

* Quality assurance

* Quality-of-life studies

* Remote data entry

* **Regulatory** consulting

* Report writing

* Site and investigator recruitment
* Study monitoring

Pharmaceutical Product Development's therapeutic experience...

19/3,K/8 (Item 8 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

1994594 Supplier Number: 01994594 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Annual Report: Leading CROs: Parexel International Corp - Ranked 5 (Parexel International is the 5th ranked contract research organization, in 1996 its worldwide net revenue was $88.0 mil)
R&D Directions, v 3, n 5, p 50+
September 1997
DOCUMENT TYPE: Journal ISSN: 1051-6778 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 1232

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...617-487-0525

Parexel's areas of expertise

Services offered by Parexel

* Case report form **design**
* Clinical consulting and training

* **Clinical trials** management

* **Data management**

* **Database design**

* Management consulting

* Outcomes

* Patient enrollment

* Pharmacoeconomics

* Phase I studies

* Phase II through Phase IV studies

* Product registration
* Protocol design

* Quality-of-life studies

* Remote data entry

* **Regulatory** consulting

* Report writing

* Site and investigator recruitment

* Statistical analysis

* Study monitoring

Parexel's therapeutic experience...

19/3,K/9 (Item 9 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

1994582 Supplier Number: 01994582 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Annual Report: Leading CROs: ClinTrials Research Inc - Ranked 4 (ClinTrials Research is the 4th ranked contract research organization, in 1996 its worldwide net revenue was $93.5 mil)
R&D Directions, v 3, n 5, p 34+
September 1997
DOCUMENT TYPE: Journal ISSN: 1051-6778 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 1192

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...areas of expertise

Services offered by ClinTrials

* Bioavailability and bioequivalence

* Biostatistical services
* Case report form **design**

* Clinical program development

* **Clinical trials** management

* **Data management**

* Patient recruitment

* Pharmacoeconomics

* Pharmacodynamics

* Pharmacokinetics

* Phase I trials

* Phase II through IV trials

* Preclinical trials
* Protocol design

* Product registrations

* Quality assurance

* **Regulatory** affairs

* Remote data entry

* Report writing

* Site and investigator recruitment

* Study monitoring

ClinTrials' therapeutic experience...

19/3,K/10 (Item 10 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

1994580 Supplier Number: 01994580 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Annual Report: Leading CROs: Clinicor Inc - Ranked 17
(Clinicor is the 17th ranked contract research organization, in 1996 its worldwide net revenue was $3.6 mil)
R&D Directions, v 3, n 5, p 32+
September 1997
DOCUMENT TYPE: Journal ISSN: 1051-6778 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 734

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...9449

Clinicor's areas of expertise

Services offered by Clinicor

* Biostatistical services
* Case report form **design**

* Clinical **data management**

* **Clinical trials** management

* Investigator recruitment

* Outcomes studies

* Patient recruitment

* Phase I clinical trials

* Phase II through IV clinical trials

* Pharmacoeconomics

* Product registration

* Protocol design
* **Regulatory** consulting

* Report writing

* Site recruitment

* Study monitoring

Clinicor's therapeutic experience

* Anesthesia

* Cardiovascular

* Central nervous system

* Dermatology

* Ear, nose, and throat

* Endocrinology
* Gastrointestinal

* Immunology

* Infectious disease

* Inflammatory **conditions**

* Musculoskeletal

* Oncology

* Ophthalmology

* Pain

* Respiratory

* Surgical ...

19/3,K/11 (Item 11 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

1994524 Supplier Number: 01994524 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Annual Report: Leading CROs: IBAH Inc - Ranked 6
(IBAH is the 6th ranked contract research organization, in 1996 its worldwide net revenue was $62.2 mil)
R&D Directions, v 3, n 5, p 43+
September 1997
DOCUMENT TYPE: Journal ISSN: 1051-6778 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 1140

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...s areas of expertise

Services offered by IBAH

* Analytical chemistry

* Biostatistical services
* Case report form **design**

* Clinical **data software**

* **Clinical trials** management

* Clinical supplies manufacturing

* Clinical supplies packaging

* Data analysis

* Formulation development

* Pathology

* Pharmacoeconomic studies

* Phase...

...Product registration
* Protocol design

* Quality assurance

* Quality-of-life studies

* Remote data entry

* Report writing

* **Regulatory** consulting

* Site and investigator recruitment

* Study monitoring

* Toxicology

IBAH's therapeutic experience

* Anesthesia
* Cardiovascular

* Central...

19/3,K/12 (Item 12 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

1994513 Supplier Number: 01994513 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Annual Report: Leading CROs: Phoenix International Life Sciences Inc - Ranked 10
(Phoenix International Life Sciences is the 10th ranked contract research organization, in 1996 its worldwide net revenue was $41.4 mil)
R&D Directions, v 3, n 5, p 58+
September 1997
DOCUMENT TYPE: Journal ISSN: 1051-6778 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 1065

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...of expertise

Services offered by Phoenix

* Animal metabolism

* Bioanalytical services
* Biostatistical analysis

* Case report form **design**

* **Clinical trials** management

* Computer-assisted new drug applications

* **Data management**

* Pharmacokinetics

* Phase I trials

* Phase II through IV trials

* Postmarketing

* Preclinical services

* **Regulatory** consulting
* Report writing

* Site and investigator recruiting

* Study monitoring

Phoenix's therapeutic experience

* Allergy

* Cardiovascular

* Central nervous system

* Dermatology

* Diagnostic imaging

* Endocrinology

* Gastrointestinal
* Hematology

* Infectious diseases

* Inflammatory **conditions**

* Metabolism

* Musculoskeletal

* Oncology

* Pain

* Respiratory

* Rheumatology ...

19/3,K/13 (Item 13 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

1994505 Supplier Number: 01994505 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Annual Report: Leading CROs: Kendle International Inc - Ranked 14 (Kendle International is the 14th ranked contract research organization, in 1996 its worldwide net revenue was $13 mil)
R&D Directions, v 3, n 5, p 46
September 1997
DOCUMENT TYPE: Journal ISSN: 1051-6778 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 892

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...the pharmaceutical and biotechnology industries.

The company's services include Phase II to Phase IV **clinical trial design** and management, clinical **data management**, biostatistical analysis, medical writing, and **regulatory** consultation. The company employs 255 people full-time.

In keeping with the company's strategy...
...Jere M. Hardy, director of clinical data management; Lois B. Rosenberger, Ph.D., director of **regulatory** affairs

Headquarters: 700 Carew Tower, Cincinnati, OH 45202; telephone 513-381-5550; facsimile: 513-381-5870

Kendle's areas of expertise

Services offered by Kendle

* Biostatistical analysis

* Case report form **design**

* Clinical trial **design**

* **Clinical trials** management

* Computer-assisted new drug applications

* **Data management**
* Database **design**

* Outcomes

* Pharmacoeconomic studies

* Phase I trials

* Phase II trials through Phase IV trials

* Postmarketing

* Protocol design

* Quality-of-life studies

* **Regulatory** consulting

* Remote data entry

* Report writing
* Safety services

* Site and investigator recruitment

* Study monitoring

Kendle...

19/3,K/14 (Item 14 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

1994499 Supplier Number: 01994499 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Annual Report: Leading CROs: Ilex Oncology Inc - Ranked 18
(Ilex Oncology is the 18th ranked contract research organization, in 1996 its worldwide net revenue was $8.1 mil)
R&D Directions, v 3, n 5, p 45+
September 1997
DOCUMENT TYPE: Journal ISSN: 1051-6778 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 778

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...8210

Ilex's areas of expertise

Services offered by Ilex

* Biostatistical analysis
* Case report form **design**

* **Clinical trial design**

* **Clinical trials** management

* **Data management**

* **Database design**

* Formulation

* Manufacturing

* Patient enrollment

* Pharmacology and toxicology

* Phase I trials

* Phase II trials and Phase III trials
* Protocol design and development

* Quality-of-life studies

* **Regulatory** consulting

* Site and investigator recruitment

* Study monitoring

Ilex's therapeutic experience

* Oncology
...

19/3,K/15 (Item 15 from file: 9)
DIALOG(R)File 9:Business & Industry(R)

1994168 Supplier Number: 01994168 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Annual Report: Leading CROs: Covalent Group Inc - Ranked 16
(Covalent Group is the 16th ranked contract research organization, in 1996 its worldwide net revenue was $10.4 mil)
R&D Directions, v 3, n 5, p 38+
September 1997
DOCUMENT TYPE: Journal ISSN: 1051-6778 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 757

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...With 20 full-time employees, Covalent designs, coordinates, and monitors clinical trials. Services include study **design** , **clinical - trial** monitoring and management, **data management** , biostatistical analysis, and **regulatory** affairs services. The company works extensively in managed-care, medical outcomes research, and health management...

...facsimile: 610-975-9556
Covalent's areas of expertise

Services offered by Covalent

* Biostatistical analysis

* **Clinical trials** monitoring and management

* Cost-effectiveness studies

* **Data management**

* Database **design** and management

* Managed-care studies

* Medical writing

* Outcomes studies

* Pharmacoeconomic studies
* Phase II through Phase IV studies

* Postmarketing studies

* Quality assurance

* **Regulatory** affairs services

* Study design

* Wellness programs

Covalent's therapeutic experience

* Anesthesia

* Cardiovascular

* Central nervous system

* Dermatology
* Ear, nose, and throat

* Endocrinology

* Gastroenterology

* Genitourinary

* Immunology

* Infectious disease

* Inflammatory **conditions**

* Metabolism

* Mental health

* Oncology

* Ophthalmology
* Pain

* Renal

* Respiratory

* Surgical

* Women's health ...

19/3,K/16 (Item 16 from file: 9)
DIALOG(R)File 9:Business & Industry(R)
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1655096 Supplier Number: 01655096 (USE FORMAT 7 OR 9 FOR FULLTEXT)
IBAH Inc.
(IBAH and its contract research business profiled; revenues, costs, earnings, company directions, priorities examined)
R&D Directions, v 2, n 3, p 30+
September 1996
DOCUMENT TYPE: Journal; Company Overview (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 1121

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...and Europe. This division's primary services include: designing product development programs, managing preclinical studies, **designing** and conducting **clinical trials** , conducting clinical **data management** and biostatistical analysis, conducting health economics analysis, and preparing **regulatory** submissions.

IBAH's contract research division generated $41.9 million in net revenue in 1995...

19/3,K/17 (Item 17 from file: 9)
DIALOG(R)File 9:Business & Industry(R)
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1376390 Supplier Number: 01376390
McKesson's buy
(McKesson Corp acquired BioServices Corp for an undisclosed sum)
Drug Topics, v 140, n 1, p 20
January 08, 1996
DOCUMENT TYPE: Journal; News Brief ISSN: 0012-6616 (United States)
LANGUAGE: English RECORD TYPE: Abstract

ABSTRACT:
...Gaithersburg, MD) for an undisclosed sum. Ogden, which is to be renamed

McKesson BioServices, provides **clinical trials** support, medical information **database design** and **regulatory** process management.
...

19/3,K/18 (Item 1 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)
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06986271 Supplier Number: 59113288 (USE FORMAT 7 FOR FULLTEXT)
PharmaResearch Corporation Announces Realignment of Executive Management Team.
Business Wire, p1545
Feb 1, 2000
Language: English Record Type: Fulltext
Document Type: Newswire; Trade
Word Count: 500

... diseases, oncology, respiratory, dermatology, gastroenterology, cardiology, and nervous system disorders, and drug development disciplines including **clinical trial design** , trial management, investigator site monitoring, **data management** , biostatistical analysis, and reporting to **regulatory** agencies. In October 1999, PharmaResearch was recognized as the 3rd fastest growing company in Research...

19/3,K/19 (Item 2 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)
(c) 2004 The Gale Group. All rts. reserv.

06803175 Supplier Number: 57527707 (USE FORMAT 7 FOR FULLTEXT)
Quintiles Signs Agreement With Chinese Pharmaceutical Company to Conduct Clinical Research for Herbal Product to Treat Stable Angina.
PR Newswire, p3287
Nov 12, 1999
Language: English Record Type: Fulltext
Document Type: Newswire; Trade
Word Count: 582

... approval of its product, Gingkonin. Those services include preparing the Investigational New Drug application, protocol **design** , **regulatory** consulting, **clinical trial** management, **data management** , data collection and analysis, report drafting and submission of a New Drug Application to the...

19/3,K/20 (Item 3 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)
(c) 2004 The Gale Group. All rts. reserv.

06574913 Supplier Number: 55497924 (USE FORMAT 7 FOR FULLTEXT)
Seattle-Based Research Firm Harnesses Internet to Develop Drugs Faster, Cheaper.
Business Wire, p0417
August 19, 1999
Language: English Record Type: Fulltext
Document Type: Newswire; Trade
Word Count: 295

... and efficacy.
Axio's Internet-based services meet the Food and Drug Administration's Enforcement **Policy** : 21 CFR Part 11; Electronic Records; Electronic Signatures **guidelines** whose purpose is to provide criteria under which the FDA will consider electronic records equivalent...

...Axio Research Corporation provides contract research services to pharmaceutical, biotechnology and biomedical companies. Services include **clinical trial design** , health **data management** , biostatistical

analysis, and Internet-based **clinical trial** management.

19/3,K/21 (Item 4 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)
(c) 2004 The Gale Group. All rts. reserv.

05357227 Supplier Number: 48148330 (USE FORMAT 7 FOR FULLTEXT)
ClinTrials Research Inc.
Pharmaceutical Executive, p16
Dec, 1997
Language: English Record Type: Fulltext
Document Type: Magazine/Journal; Trade
Word Count: 357

... projects, as well as conducted single-continent and country-specific projects ultimately resulting in successful **regulatory** filings.
Our experienced, multilingual staff conducts trials following companywide Standard Operating Procedures. Worldwide electronic mail...

...Services
ClinTrials Research's full-service global capabilities include preclinical services; clinical program development; study **design** ; worldwide **clinical trials** management; program management; clinical monitoring; **data management** ; biostatistics; quality assurance; medical communications; **regulatory** affairs; pharmacoeconomic studies; institutional review board/ethical committees; broad therapeutic experience; megatrial experience; and ClinLink...

19/3,K/22 (Item 5 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)
(c) 2004 The Gale Group. All rts. reserv.

03335810 Supplier Number: 44615260 (USE FORMAT 7 FOR FULLTEXT)
QUINTILES TRANSNATIONAL CORP. IPO TRADING BEGINS
PR Newswire, pN/A
April 21, 1994
Language: English Record Type: Fulltext
Document Type: Newswire; Trade
Word Count: 253

... has been profitable every year since the company was founded in 1982. Quintiles' services include **clinical trials** management, **data management** , biostatistical analysis, centralized **clinical trial** laboratory services, preclinical testing, study **design** , strategic and **regulatory** consulting, and health economics consulting.
Copies of the prospectus can be obtained from the office...

19/3,K/23 (Item 1 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB
(c)2004 The Gale Group. All rts. reserv.

08340218 SUPPLIER NUMBER: 17889994 (USE FORMAT 7 OR 9 FOR FULL TEXT)
McKesson Corp. Acquires Bioservices Subsidiary of Ogden Corporation.
Business Wire, p12200030
Dec 20, 1995
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 458 LINE COUNT: 00047

... reporting to David L. Mahoney, McKesson corporate vice president.
"Through the services it provides for **clinical trials** support, **regulatory** process management and medical information **database design**

on the pre-approval side of drug development," Mahoney said, "McKesson BioServices will complement the...

19/3,K/24 (Item 2 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB

07205603 SUPPLIER NUMBER: 14928578 (USE FORMAT 7 OR 9 FOR FULL TEXT)
QUINTILES APPOINTS FORMER GLAXO EXECUTIVE AS CHIEF OPERATING OFFICER
PR Newswire, p0323CH010
March 23, 1994
LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT
WORD COUNT: 380 LINE COUNT: 00034

... development services on a global basis for the pharmaceutical and biotechnology industries. These services include **clinical trials** management, **data management** , biostatistical analysis, centralized **clinical trial** laboratory services, preclinical testing, study **design** , strategic and **regulatory** consulting, and health economics consulting.
-0- 3/23/94
/CONTACT: Sara Creagh, Executive Vice President...

19/3,K/25 (Item 1 from file: 20)
DIALOG(R)File 20:Dialog Global Reporter

08202167 (USE FORMAT 7 OR 9 FOR FULLTEXT)
(CNW) Quintiles Signs Agreement With Chinese Pharmaceutical Company to Conduct Clinical Research for Herbal Product to Treat Stable Angina
CANADA NEWSWIRE
November 12, 1999
JOURNAL CODE: WCNW LANGUAGE: English RECORD TYPE: FULLTEXT
WORD COUNT: 599

... approval of its product, Gingkonin. Those services include preparing the Investigational New Drug application, protocol **design** , **regulatory** consulting, **clinical trial** management, **data management** , data collection and analysis, report drafting and submission of a New Drug Application to the...

19/3,K/26 (Item 1 from file: 149)
DIALOG(R)File 149:TGG Health&Wellness DB(SM)

01482163 SUPPLIER NUMBER: 15430566 (USE FORMAT 7 OR 9 FOR FULL TEXT)
An acute care physical therapy clinical practice database for outcomes research. (Special Issue: Physical Disability)
Shields, Richard K.; Leo, Ken C.; Miller, Bruce; Dostal, William F.; Barr, Rhonda
Physical Therapy, v74, n5, p94(8)
May,
1994
PUBLICATION FORMAT: Magazine/Journal ISSN: 0031-9023 LANGUAGE: English
RECORD TYPE: Fulltext; Abstract TARGET AUDIENCE: Professional
WORD COUNT: 5339 LINE COUNT: 00477

... a Type I error. Through the database, a source of valuable information is available when **designing** randomized **clinical trials** . The **database** also provides an efficient projection of the patients available within an institution when proposing clinical...

...PTCMR has been operational since August 1991. All staff (37 therapists) have been in full **compliance** with the computerized system. We believe this **compliance** is particularly due to the therapists' involvement during the developmental stages. Studies indicate that the...

19/3,K/27 (Item 2 from file: 149)
DIALOG(R)File 149:TGG Health&Wellness DB(SM)

01359925 SUPPLIER NUMBER: 12339443 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Contemporary clinical trials in acute respiratory distress syndrome. (Special Report)
Petty, Thomas L.; Bone, Roger C.; Gee, Marlys H.; Hudson, Leonard D.; Hyers, Thomas M.
Chest, v101, n2, p550(3)
Feb,
1992
PUBLICATION FORMAT: Magazine/Journal ISSN: 0012-3692 LANGUAGE: English
RECORD TYPE: Fulltext TARGET AUDIENCE: Professional
WORD COUNT: 2191 LINE COUNT: 00181

... relationships among academics, industry, and the NIH. The concept of using established NIH procedures as **guidelines** for consensus conferences on protocol **design** , peer review, and **data management** to aid in industry-supported **clinical trials** should be explored.
The Division of Lung Diseases does have an ongoing program to support ...

19/3,K/28 (Item 1 from file: 43)
DIALOG(R)File 43:Health News Daily - Subs

00026156 F-D-C Accession Number 03090030003
Health News Daily -- January 6, 1997
Volume 9, Issue 3

Summit Medical broadens consulting service through C.L. McIntosh buy; stock deal expected to help McIntosh expand clinical trial services in biologics, firm says.

MANUFACTURER: Biometric Sciences ; Blood Institute ; C L Mcintosh ; Center For Devices ; FDA 's Center for Biologics Evaluation and Research ; FDA 's Office of Compliance and Surveillance ; FDA 's Office of Device Evaluation Robert Sheridan ; McIntosh ; Regulatory Affairs Professionals Society ; Standards Enforcement ; SUMMIT MEDICAL SYSTEMS' ACQUISITION OF C L MCINTOSH & ASSOCIATES

... Summit's Vista Elite software package to guide its clients -- primarily medical device firms -- on **regulatory** submission and **clinical trial design** issues.
"Summit Medical's advances in **database** technology...was one key factor in our selecting to merge with Summit," Charles McIntosh, president...
... a Jan. 2 release. "The opportunity to introduce their information technology to medical and device **regulatory** processes, with its traditionally labor-intensive data acquisition and analysis, provides" the company with a...

19/3,K/29 (Item 1 from file: 624)
DIALOG(R)File 624:McGraw-Hill Publications

00879067
KENDLE INT'L BUY
S&P's Emerging & Special Situations August 18, 1997; Pg 15; Vol. 17, No. 8
Journal Code: ESS ISSN: 0882-5440
Section Heading: NEW AND NOTEWORTHY
Word Count: 627 *Full text available in Formats 5, 7 and 9*

TEXT:

...above their earnings growth rates.

The company's drug delivery and information tracking services include **clinical trial design** and management, clinical **data management** , biostatistical analysis, medical writing and **regulatory** consultation and representation. Since, inception, it has served more than 40 clients, including 12 of...

19/3,K/30 (Item 1 from file: 635)
DIALOG(R)File 635:Business Dateline(R)

0659046 96-15879
McKesson Corp. acquires BioServices subsidiary of Ogden Corporation
Reutlinger, Annie
Business Wire (San Francisco, CA, US) s1 p1
PUBL DATE: 951220
WORD COUNT: 433
DATELINE: San Francisco, CA, US, Pacific

TEXT:

...reporting to David L. Mahoney, McKesson corporate vice president.

"Through the services it provides for **clinical trials** support, **regulatory** process management and medical information **database design** on the pre-approval side of drug development," Mahoney said, "McKesson BioServices will complement the...

19/3,K/31 (Item 2 from file: 635)
DIALOG(R)File 635:Business Dateline(R)

0480192 94-33907
Quintiles appoints former Glaxo executive as chief operating officer
Creagh, Sara
PR Newswire (New York, NY, US) s1 p1
PUBL DATE: 940323
WORD COUNT: 315
DATELINE: Research Triangle Park, NC, US

TEXT:

...development services on a global basis for the pharmaceutical and biotechnology industries. These services include **clinical trials** management, **data management** , biostatistical analysis, centralized **clinical trial** laboratory services, preclinical testing, study **design** , strategic and **regulatory** consulting, and health economics consulting.

8/3,K/1 (Item 1 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

06940128 Supplier Number: 58610938 (USE FORMAT 7 FOR FULLTEXT)
Barnett International Announces Spring Semester Of Clinical Research Training Programs.
PR Newswire, p2899
Jan 17, 2000
Language: English Record Type: Fulltext
Document Type: Newswire; Trade
Word Count: 579

... the worldwide pharmaceutical, biotechnology, and medical device industries and to the academic community. Over the past fifteen years, PAREXEL has **developed** significant expertise in **clinical trials** management, **data management** , biostatistical analysis, medical marketing, clinical pharmacology, regulatory and medical consulting, industry training, publishing and other drug development consulting services. PAREXEL...

...to develop a pediatric clinical research initiative to respond to the recently enacted FDA Modernization Act and the Final Pediatric **Rule** . Headquartered near Boston, MA, PAREXEL has approximately 4,400 employees in 48 offices throughout 29 countries around the world.
This...

8/3,K/2 (Item 2 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

06921464 Supplier Number: 58503282 (USE FORMAT 7 FOR FULLTEXT)
PAREXEL Announces Collaborative Agreement With PCTI.
PR Newswire, p7859
Jan 10, 2000
Language: English Record Type: Fulltext
Document Type: Newswire; Trade
Word Count: 760

... the worldwide pharmaceutical, biotechnology, and medical device industries and to the academic community. Over the past fifteen years, PAREXEL has **developed** significant expertise in **clinical trials** management, **data management** , biostatistical analysis, medical marketing, clinical pharmacology, regulatory and medical consulting, industry training, publishing and other drug development consulting services. PAREXEL...

...to develop a pediatric clinical research initiative to respond to the recently enacted FDA Modernization Act and the Final Pediatric **Rule** . Headquartered near Boston, MA, PAREXEL has approximately 4,400 employees in 48 offices throughout 29 countries around the world.
Columbus...

8/3,K/3 (Item 3 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

06921457 Supplier Number: 58503275 (USE FORMAT 7 FOR FULLTEXT)
PAREXEL Names Ronald E. Keeney, M.D., as Head of Pediatric Clinical Research.
PR Newswire, p7852
Jan 10, 2000
Language: English Record Type: Fulltext
Document Type: Newswire; Trade
Word Count: 590

... the worldwide pharmaceutical, biotechnology, and medical device industries and to the academic community. Over the past fifteen years, PAREXEL has **developed** significant expertise in **clinical trials** management, **data management** , biostatistical analysis, medical marketing, clinical pharmacology, regulatory and medical consulting, industry training, publishing and other drug development consulting services. PAREXEL...

...to develop a pediatric clinical research initiative to respond to the recently enacted FDA Modernization Act and the Final Pediatric **Rule** . Headquartered near Boston, MA, PAREXEL has approximately 4,400 employees in 48 offices throughout 29 countries around the world.

8/3,K/4 (Item 1 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB

10117336 SUPPLIER NUMBER: 20430883 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Implementing the FDA Modernization Act. (Medical News & Perspectives)
Marwick, Charles
JAMA, The Journal of the American Medical Association, v279, n11, p815(2)
March 18, 1998
ISSN: 0098-7484 LANGUAGE: English RECORD TYPE: Fulltext; Abstract
WORD COUNT: 1576 LINE COUNT: 00124

Holston cited requirements for changes in drug label information, **development** of a **clinical trial database** , improved patient access to drugs, and new consideration of pharmacy compounding among the principal provisions.

A measure of the extent...

...will require 42 new regulations, most of which must be issued as proposals with time for comment before a final **rule** is published. There will have to be at least 23 new guidance notices, and 45 reports and other tasks, said...

8/3,K/5 (Item 1 from file: 47)
DIALOG(R)File 47:Gale Group Magazine DB(TM)

05147754 SUPPLIER NUMBER: 20297396 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Pulmonary infiltrates, eosinophilia, and cardiomyopathy following corticosteroid withdrawal in patients with asthma receiving zafirlukast.
Wechsler, Michael E.; Garpestad, Erik; Flier, Steven R.; Kocher, Olivier; Weiland, David A.; Polito, Albert J.; Klinek, Michelle M.; Bigby, Timothy D.; Wong, Gordon A.; Helmers, Richard A.; Drazen, Jeffrey M.
JAMA, The Journal of the American Medical Association, v279, n6, p455(3)
Feb 11, 1998
ISSN: 0098-7484 LANGUAGE: English RECORD TYPE: Fulltext; Abstract
WORD COUNT: 2705 LINE COUNT: 00239

... a vasculitic response. The lack of such episodes in the more than 6000 asthma patients exposed to the drug during **clinical trials** does not **rule** out this possibility, given the overall low incidence of the syndrome. Furthermore, since patients receiving zafirlukast treatment are asthmatic and...

...component of the syndrome, allowing unmasking of an underlying eosinophilic infiltrative process. Such a mechanism has been proposed previously for **formes** frustes cases of Churg-Strauss syndrome, and one could easily classify these cases under such a rubric; indeed, such a...
...of this cohort of patients.(15) Evidence for this mechanism derives from the fact that all of the people who **developed** the syndrome had been dependent on steroids, while no non-steroid-dependent patients **developed** similar symptoms. Indeed, we speculate that if this unmasking is the clinical mechanism involved, this syndrome may occur rarely in patients

treated with any leukotiriene receptor antagonist. Whether this syndrome will **develop** when the synthesis of leukotrienes is inhibited rather than when their actions are antagonized is not known.

Zafirlukast is a...A. Kozina, MD, and Michael A. Davis, MD, Department of Medicine, Mercy General Hospital, Sacramento, Calif.

References

(1.) The Accolate **Clinical Trials Database** 1996. Wilmington, Del: Zeneca Pharmaceuticals; 1996.

(2.) National Prescription Audit (NPA+). Plymouth Meeting, Pa: IMS America Ltd; 1997.

(3.) Weller...

File 9:Business & Industry(R) Jul/1994-2004/Sep 07
(c) 2004 The Gale Group
File 16:Gale Group PROMT(R) 1990-2004/Sep 08
(c) 2004 The Gale Group
File 160:Gale Group PROMT(R) 1972-1989
(c) 1999 The Gale Group
File 148:Gale Group Trade & Industry DB 1976-2004/Sep 07
(c)2004 The Gale Group
File 621:Gale Group New Prod.Annou.(R) 1985-2004/Sep 07
(c) 2004 The Gale Group
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(c) 2004 ESPICOM Bus.Intell.
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(c) 2004 NewsRx
File 187:F-D-C REPORTS 200408W5 - 200409W1
(c) 2004 F-D-C Reports Inc.
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(c) 2004 The Gale Group
File 47:Gale Group Magazine DB(TM) 1959-2004/Sep 07
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(c) 2004 McGraw-Hill Co. Inc
File 553:Wilson Bus. Abs. FullText 1982-2004/Jul
(c) 2004 The HW Wilson Co
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(c) 2004 ProQuest Info&Learning
File 810:Business Wire 1986-1999/Feb 28
(c) 1999 Business Wire
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(c) 2004 CMP Media, LLC
File 674:Computer News Fulltext 1989-2004/Aug W3
(c) 2004 IDG Communications
File 696:DIALOG Telecom. Newsletters 1995-2004/Sep 07
(c) 2004 The Dialog Corp.
File 369:New Scientist 1994-2004/Aug W5
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File 634:San Jose Mercury Jun 1985-2004/Sep 07
(c) 2004 San Jose Mercury News
File 370:Science 1996-1999/Jul W3
(c) 1999 AAAS
File 613:PR Newswire 1999-2004/Sep 08
(c) 2004 PR Newswire Association Inc
File 610:Business Wire 1999-2004/Sep 08
(c) 2004 Business Wire.

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S1	617641	(CLINICAL OR CLINICIAN OR MEDICAL OR MEDICINAL OR HOSPITAL OR PHARMACEUTICAL OR DRUG)(1W)(TRIAL? ? OR TEST? ?)
S2	6795	S1(7N)(DATABASE? ? OR DATA()BASE? ? OR (INFORMATION OR DATA)(1W)(MANAGEMENT OR MANAGER) OR REPOSITOR??? OR DBMS OR RDBMS

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              OR (MANAGEMENT OR INFORMATION OR DATA)()(SYSTEM OR SOFTWARE))
S3       1594   S2(5N)(ESTABLISH? OR GENERAT? OR CREAT???? OR FASHION? OR -
                CONSTRUCT? OR FORM?? OR FORMING OR FORMATION? ? OR PRODUC?????
                OR DEVELOP? OR BUILT OR BUILD? OR DEFIN??? OR SET????()UP)
S4        873   S3(50N)(RULE? ? OR REGULATION? ? OR REGULATORY OR POLICY OR
                POLICIES OR COMPLIANT OR COMPLIANCE OR GUIDELINE? ? OR CONDI-
                TION? ?)
S5        319   RD (unique items)
S6        154   S5 NOT PY=2001:2004
S7         22   S3(50N)RULE? ?
S8          5   RD (unique items)
S9     272743   (VERIF???? OR VERIFICATION OR VALIDAT???? OR CHECK??? OR C-
                ONFIRM??? OR CONFIRMATION)(15N)(REGULATION? ? OR REGULATORY OR
                POLICY OR POLICIES OR COMPLIANT OR COMPLIANCE OR GUIDELINE? ?
                OR CONDITION? ?)
S10         5   S3(100N)S9
S11        45   S2(50N)(RULE OR RULES)
S12        17   RD (unique items)
S13        12   S12 NOT S8
S14      1376   PHASE()FORWARD
S15         2   S14 AND PREDICATE()RULE? ?
S16       296   S2(5N)DESIGN???
S17        81   S16(50N)(RULE? ? OR REGULATION? ? OR REGULATORY OR POLICY -
                OR POLICIES OR COMPLIANT OR COMPLIANCE OR GUIDELINE? ? OR CON-
                DITION? ?)
S18        44   RD (unique items)
S19        31   S18 NOT PY=2001:2004
S20         5   ((PHASE()FORWARD)(1W)TRW)/TI
S21         1   RD (unique items)
S22        41   PHASE()FORWARD AND INFORM()ARCHITECT
S23        17   RD (unique items)
S24        17   Sort S23/ALL/PD,A
S25         6   PHASE()FORWARD AND CRF()SUBMIT
S26         3   RD (unique items)
S27        27   S14(100N)RULE? ?
S28         7   RD (unique items)
S29         5   S28 NOT PY=2001:2004
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